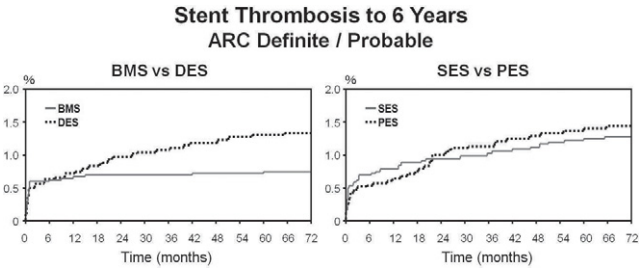
myocardial infarction after stent thrombosis in both groups.



Conclusion: The incidence of stent thrombosis in Asian races is relatively low (0.5 % with DES and 0.6% with BMS of SAT, 0.18% increase per year with DES of late stent thrombosis) at mean follow-up to 6 years. Particular attention will need to be directed to this complication when the patients have bifurcation lesions or low ejection fraction.

TCT-211

The SYNTAX Trial at 3 Years: A Global Risk Approach to Identify Patients With 3-Vessel &/or Left Main Stem Disease Who Could Safely & Efficaciously Be Treated With Percutaneous Coronary Intervention Part 2: The All-Comers SYNTAX Population

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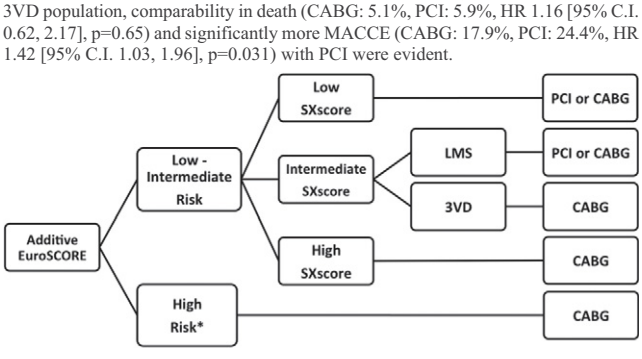
Background: The Global Risk Categorisation (GRC), a combination of the SYNTAX score (SXscore) & additive EuroSCORE, is superior to the SXscore alone in predicting clinical outcomes in patients with 3VD &/or LMS coronary disease undergoing PCI. The GRC is investigated in the All-Comers "real-world" SYNTAX population.
Methods: The study population (n=3075) consisted of pre-specified powered randomised LMS & 3VD cohorts (n=1800) & non-randomisable nested CABG (n=649/1077 randomly selected patients) & PCI (n=198) registries. The primary (all-cause-death) & secondary (MACCE) endpoints at 36-months were analysed in pre-defined low (n=1156), intermediate (n=1098) & high (n=356) risk categories.
Results: Baseline characteristics demonstrated significantly more adverse co-morbidity within the All-Comers PCI population & more complex anatomy within the All-Comers CABG population. At 36-months, within the LMS & 3VD All-Comers PCI cohorts, the GRC separated a low risk (GRClow) group from the higher risk (GRCint) group, for death & MACCE. Within the All-Comers CABG population, significant differences between GRCint-high only were evident for death & MACCE. Comparative analyses, between CABG & PCI in the GRClow LMS cohort, revealed no statistically significant differences in death (CABG: 5.3%, PCI: 2.7%, HR 0.51 [95% C.I. 0.18, 1.44], p=0.19) & MACCE (CABG: 18.0%, PCI: 18.5%, HR 1.02 [95% C.I. 0.65, 1.60], p=0.94), contrary to the randomized findings. Within the GRClow 3VD population, comparability in death (CABG: 5.1%, PCI: 5.9%, HR 1.16 [95% C.I. 0.62, 2.17], p=0.65) and significantly more MACCE (CABG: 17.9%, PCI: 24.4%, HR 1.42 [95% C.I. 1.03, 1.96], p=0.031) with PCI were evident.



Proposed Algorithm

Conclusion: The identification of low Global Risk patients within the All-Comers SYNTAX population, reflecting "real-life" contemporary practice, maintains its clinical usefulness in risk stratifying patients.

TCT-212

Are Results from an All-Comers Registry Comparable with the Results from an All-Comers Randomized Clinical Trial? Insights from 12-Month Results of the e-BioMatrix PMS Registry

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Background: The safety and effectiveness of Biolimus A9™-eluting stents (BES) has been evaluated relative to sirolimus-eluting stents in the LEADERS all-comers RCT and in several observational registries. We compared the 1-year results for the first 1102 patients in the e-BioMatrix registry with the 857 patients in the BES arm of LEADERS and analysed how the different study designs impacted the results.
Methods: Both the e-BioMatrix PMS registry and the LEADERS RCT are all-comers, "real world" studies, not limited by lesion length, number of treated lesions/vessels or clinical indication (chronic stable angina vs. ACS). The baseline characteristics were similar (ex. mean age: 64.1 vs. 64.6 (p=0.35), DM: 24% vs. 26% (p=0.32), ACS: 53% vs. 55% (p=0.41), STEMI: 16% vs 19% (p=0.05)). LEADERS had higher proportions of patients with prior PCI and prior MI (36% vs 25% (p<0.001) and 32% vs 21% (p<0.001)). We compared the rates of cardiac death, MI, clinically-indicated TVR and ARC-defined stent thrombosis at 12 months.
Results: The patients enrolled in the e-BioMatrix registry had similar rates of cardiac death (1.7% vs 2.1%) and QW MI (0.5% vs 0.5%) compared to those in LEADERS, but exhibited lower rates of all MI (2.5% vs. 5.8%, p<0.001), and a trend towards lower clinically-indicated TVR (4.3% vs 5.8%, p=0.12) at 1 year. The 1-year MACE rates were 6.7% and 10.6% for e-BioMatrix and LEADERS respectively (p<0.01). Although e-BioMatrix showed a lower rate of early definite ST vs LEADERS (0.5% vs 1.6%, p<0.05), the rates of late ST were similar (0.4% vs 0.4%).
Conclusion: The e-BioMatrix PMS registry confirms the good safety profile of BES at 12 months. Even though LEADERS was an "all-comers" study, some of the adverse event rates were lower in the e-BioMatrix registry, especially during the first 30 days, consistent with a patient selection process and a per protocol analysis (vs. ITT in LEADERS). This could be related to mandatory ECG and biomarker determinations required post-procedure in LEADERS together with different MI definitions. A 25% rate of protocol mandated angiographic FU may also contributed to higher rates of peri-procedural MI and TVR. However, the near identical event rates beyond 30 days for all components of MACE, suggest that under-reporting of events is unlikely to have played a major role.

TCT-213

Increased Tissue Stress Leads to Increased Neointima Evaluated by Histology and Computational Modeling

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Background: The biomechanical performance of stenting can be best understood through a coupling of computational modeling with in vivo pathology evaluations. To this end, finite element analysis (FEA) of stent-artery interaction can be used to characterize vessel-specific stresses and their correlation to biologic response.
Methods: Two bare-metal stent designs differing in strut thickness were compared for differences in vessel wall stress. FEA was used to simulate the deployment of both stent models in a mock artery model. Acute and chronic stresses induced in the vessel wall were determined and compared between stent models. Stents (n=4) were implanted in a normal rabbit iliac artery at 1.3:1 stent:artery ratio. Twenty-eight days following stenting, histomorphometric analysis was performed.
Results: Stresses were ~70% lower for thin versus thick stents. Overall, there was increased neointimal area in the thick versus thin stents (0.86±0.07 vs 0.66±0.10 p=0.02). Though neointimal thickness above struts trended lower in thick struts (0.02±0.00 vs 0.03±0.01, p=0.08), the change in neointimal thickness immediately adjacent to struts was greater in thick struts (0.18±0.00 vs 0.11±0.01 p<0.01). Neointimal thickness was similar between the two groups between struts (0.07±0.02 vs 0.03±0.01 p=0.67).

Table 1: FEA predicted principal stress (PS) and Von Mises stress (VM) at stent crest locations.

	"U" crest (N=15)		"W" crest (N=6)		"Y" crest (N=3)	
	PS (psi)	VM (psi)	PS (psi)	VM (psi)	PS (psi)	VM (psi)
VISION 2x (Thick)	804.4	1396.4	211.1	395.4	232.1	362.1
VISION 1x (Thin)	112.2	275.3	85.9	161.4	90.5	140.5
Percent drop in stress	86%	80%	59%	59%	61%	61%

Conclusion: Stent design impacts the stress induced in the vessel wall during and after stent deployment. Von Mises and principal stresses are focused at stent strut contact

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locations, while further away principal stresses predominate. Increased neointimal thickness seems to relate to increased von Mises stresses at the site of stent struts. Evaluating induced tissue stresses with stent-artery interaction models may improve future device designs.

TCT-214

Safety and Effectiveness of Everolimus-Eluting Stents in 5054 Patients from a Large, Prospective, Real World Study: Two-Year Clinical Outcomes from the XIENCE V® USA Study

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Background: The safety and effectiveness of XIENCE V® everolimus-eluting stents (XIENCE V, Abbott Vascular, Santa Clara, CA) at 1 year (1Y) in real world clinical settings have been demonstrated in XIENCE V USA trial with low rates of target lesion revascularization (TLR), cardiac death, MI and stent thrombosis (ST). Data on whether these results are maintained through longer follow-up have not yet been reported.
Methods: XIENCE V USA is a prospective, multicenter, single-arm, FDA required condition of approval study designed to examine the safety and effectiveness of XIENCE V in an all-inclusive, consecutively-enrolled population from real world clinical settings. Clinical endpoint events, including ST, cardiac death, MI, and revascularization were adjudicated by an independent Clinical Events Committee.
Results: A total of 4382 patients completed 2-year (2Y) follow up. Baseline Characteristics and Clinical Outcomes through 2Y appear in the table below.

Baseline Characteristics and Clinical Outcomes through 2 Years

Baseline Characteristics		
Age in years	64.74	
Female	31.2 %	
Diabetes	35.6 %	
ACS	36.7 %	
AMI	16.0 %	
Restenotic Lesions	9.5 %	
Bifurcations	9.2 %	
Ostial Lesions	11.8 %	
DAPT Usage and Clinical Outcomes		
	1 Year (0-365 days)	**2 Years (0-730 days)**
DAPT Usage	82.2 %	64.1 %
ARC Def/Prob Stent Thrombosis	0.87 %	0.96 %
ARC MI [1]	5.6 %	7.2 %
WHO MI [2]	2.1 %	2.7 %
Cardiac Death	1.5 %	2.5 %
Cardiac Death and ARC MI	6.6 %	8.9 %
Cardiac Death and WHO MI	3.3 %	4.7 %
TLF [3] (ARC MI component)	8.6 %	12.1 %
TLF (WHO MI component)	6.5 %	10.0 %
TLR	4.4 %	7.0 %

[1]ARC MI definition: elevation of troponin or CKMB > 3 URL for periprocedual PCI, > 5 URL for periprocedual CABG, and > 1 URL for spontaneous MI

[2]WHO MI definition: QMI per ECG or elevation of CK ≥ 2 URL with elevated CKMB in the absence of new pathological Q waves

[3]TLF: composite of cardiac death, MI attributed to target vessel, and clinically-indicated TLR

Conclusion: Low event rates observed at 1Y were maintained through 2Y. Of note, despite the increased number of patients who discontinued DAPT by 2 Y, the ST rate remained consistently low, and <1% at 2Y. These results demonstrate continued safety and effectiveness of the XIENCE V in a highly complex, real world patient population through 2Y.

TCT-215

STEALTH I: 5-year Follow-up from a Prospective Randomized Study of Biolimus A9™-Eluting Stent with a Biodegradable Polymer Coating vs a Bare Metal Stent

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Background: The purpose of the STEALTH I trial was to assess the safety and efficacy of the Biolimus A9™-eluting stent with a biodegradable polymer coating (BioMatrix™), as compared to a bare metal control stent (S-Stent™). The purpose of this presentation is to present the 5 year and final report of this study.
Methods: This is a prospective, randomized, double-blind study which enrolled patients in 3 centers in Germany (2) and Brazil. A total of 120 patients were enrolled and randomly allocated 2:1 to receive the BioMatrix stent (BES) or the S-Stent (BMS). The primary endpoint was in-stent late loss at 6 months. Secondary endpoints include MACE defined as a composite of death, myocardial infarction, and target lesion revascularization at 30 days, 3, 6 months, 1 year and then yearly up to 5 years. Angiographic follow-up (measured by QCA) was protocol mandated at 6 months. IVUS was performed immediately post-procedure and at 6 months.
Results: The mean age for BES patients was 62.2 ±10 years, 60.0% were male; 26.6% had a history of diabetes mellitus. The in-stent late loss at 6 months was 0.19 mm ± 0.39 mm for BES patients compared to 0.76 mm (± 0.45 mm) for BMS patients (p<0.001). In-segment late loss was 0.09 ± 0.31 (BES) vs. 0.48 ± 0.43 (BMS), p<0.001. Out to 5 years a MACE event occurred in 13 patients (18.1%) for BES compared to 4 patients (10.5%) treated with a BMS (p =0.41). There was 1 acute and one late stent thrombosis (protocol-defined) in the BES group.
Conclusion: The BioMatrix stent demonstrated statistical superiority for both in-segment and in-stent late loss at 6 months compared to the bare metal control stent. This benefit was achieved without an increase in adverse safety outcomes assessed. The long-term clinical results demonstrate that the BioMatrix stent maintains an adequate safety profile equal with conventional bare metal stents.

TCT-216

In-Hospital Experience of "Real World" Patients Enrolled in the TAXUS Liberte Post-Approval Study: The TAXUS Liberte Stent with Concomitant Prasugrel Therapy

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Background: Information is lacking regarding prasugrel use following TAXUS Liberte stent implantation in routine clinical practice.
Methods: The TAXUS Liberte Post-Approval Study is a prospective, multicenter registry that will examine 5-year clinical outcomes in patients with implanted TAXUS Liberte stents with concomitant prasugrel therapy. Enrollment of approximately 4200 total patients at up to 100 sites is planned. Following an initial enrollment of 3600 planned "real world" patients, an additional 600 patients with restricted eligibility criteria will be enrolled. Once stented, patients will be prescribed aspirin and prasugrel (at 5 mg or 10 mg doses, as appropriate) for 12 months, followed by 1:1 randomization to either continued prasugrel or placebo for an additional 18 months. This presentation will evaluate the in-hospital experience of the "real-world" patient cohort. Where appropriate, comparisons will be made to the TAXUS ARRIVE registry, which enrolled 7492 "real world" patients receiving the previous generation TAXUS Express-2 stent between 2004 and 2005.
Results: Enrollment of approximately 3600 "real world" patients was completed in March 2011 and data are currently being analyzed. The presentation will include: (1) patient demographics and procedural characteristics, compared across the TAXUS Liberte and TAXUS ARRIVE registries; (2) data regarding prasugrel dose and usage rates, including drug switching, in the TAXUS Liberte registry; (3) in-hospital major adverse cardiac events (MACE; defined as cardiac death, myocardial infarction, and target vessel revascularization) and stent thrombosis in the TAXUS Liberte registry compared to TAXUS ARRIVE; and (4) cerebrovascular event rates and bleeding (defined per GUSTO criteria) in the TAXUS Liberte registry.
Conclusion: The TAXUS Liberte Post-Approval Study will be the first to assess prasugrel use in "real world" patients receiving the TAXUS Liberté stent. This abstract will present the initial experience of this study, including in-hospital MACE, cerebrovascular events, and bleeding data.

TCT-217

Impact of Total Stent Length Per Patient and Per Lesion On Five-Year Clinical Outcomes

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Background: The sirolimus-eluting stent (SES) has reduced the rate of restenosis compared to use of the bare-metal stent for longer stented segments. The object of the study was to examine the relationships of total stent length (TSL) per patient and per lesion with target lesion revascularization (TLR) and stent thrombosis (ST) at 5 years.
Methods: The j-Cypher Registry includes consecutive patients receiving a SES in 37 centers in Japan. By February 2011, 5-year follow-up data were available for 10,773 patients and 17,040 lesions with exclusively SES implantation. The patients and lesions were divided into four groups according to quartiles for TSL per patient or per lesion: Q1: TSL-P 8-18 mm, N=2,819; Q2: TSL-P 19-28 mm, N=2,570; Q3: TSL-P 28-51 mm, N=2,929; Q4: TSL-P 52-293 mm, N=2,455; QA: TSL-L 8-18 mm, N=6,167; QB: TSL-L 19-23 mm, N=4,040; QC: TSL-L 23-33 mm, N=2,790; QD: TSL-L 33-150 mm, N=4,043.
Results: The 5-year TLR rates were 8.8% in Q1, 9.8% in Q2, 14.1% in Q3 and 22.2% in Q4 (p<0.0001); and 8.4% in QA, 9.1% in QB, 10.8% in QC and 17.4% in QD (p<0.0001). The 5-year definite/probable ST per patient rates were 1.24% in Q1, 1.28% in Q2, 1.88% in Q3 and 2.32% in Q4 (p<0.023); and definite stent thrombosis per lesion rates were 0.88% in QA, 0.79% in QB, 1.00% in QC and 1.41% in QD (p=0.0228).